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Complete versus culprit-only revascularization strategies to treat multi-vessel disease after primary percutaneous coronary interventions (PCI) for ST-segment elevation myocardial infarction

Submission date	Recruitment status	[_] Prospectively registered
16/01/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/04/2021	Circulatory System	

Plain English summary of protocol

Background and study aims

It is common practice to treat patients with a heart attack affecting much of the heart muscle, known as an ST-segment elevation myocardial infarction (STEMI), with percutaneous coronary intervention (PCI). PCI for STEMI can be either primary PCI or rescue PCI or a pharmacoinvasive strategy. Doctors trained to carry out this procedure are called interventionists. Interventionists identify the 'culprit' lesion, which is the blocked coronary artery responsible for the heart attack, clear any blood clot, and usually site a small device known as a stent in the artery to keep it open and allow the blood to flow freely to the heart muscle (revascularisation). The amount of disease varies from patient to patient. Some patients will have remaining narrowing in arteries that have not actually caused the heart attack. These narrowings are referred to as 'non-culprit lesions'. Following PCI, some interventionists will treat these patients with medical therapy and only if the patients come with worsening symptoms will consider looking at the arteries again. However, other interventionists, following primary PCI, will treat the patient with medication, and in addition, plan to bring the patient back to the lab in the near future to treat the non-culprit lesions ('staged PCI'), which may minimise the risk of further heart disease. This study is looking at both of the treatment strategies described above to find out whether a strategy of complete revascularisation will be better than a strategy of culprit-lesion-only revascularisation.

Who can participate?

Patients who have undergone primary PCI will be invited to participate in the study within 72 hours of their procedure.

What does the study involve?

Patients are randomly allocated to one of two treatment groups: complete revascularisation or

culprit-only revascularisation. Those allocated to complete revascularisation will undergo staged PCI, within 45 days, of all suitable non-culprit lesions. Those allocated to undergo the culprit-only revascularisation will be treated if they have worsening symptoms in future.

What are the possible benefits and risks of participating?
All patients will receive a very high level of treatment and follow-up by trained doctors. You will be followed carefully at regular intervals by the research team involved in the study. Your medications will be reviewed at regular intervals and you will also have your cholesterol levels and blood pressure checked. An additional PCI procedure carries a small risk (about 1 in 100) of procedure-related complications such as heart attack, stroke or death. This risk will be higher or lower in some patients, depending on their age and other factors. In addition, there is a small risk of the contrast dye affecting the kidneys (less than 1 in 100) and allergic reaction to the contrast dye (less than 1 in 100). This study is being conducted to find out if an additional PCI procedure will lower your long-term risk of subsequent heart attack or death. The additional PCI procedure you might receive will give you a dose of ionising radiation equivalent to about 2 years average natural background radiation. The Health Protection Agency (now Public Health England) Radiation Protection Division describe a radiation exposure equivalent to a few years average natural background radiation as Low Risk. For some patients the second procedure would not be additional, and hence no additional risk.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust is the UK lead site.

When is the study starting and how long is it expected to run for?
The study started recruitment in the UK in January 2013 and will run for 5 years.

Who is funding the study?
1. Astra Zeneca (Canada)
2. Boston Scientific (USA)
3. Population Health Research Institute (Canada)

Who is the main contact?
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Type(s)
Scientific

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ClinicalTrials.gov (NCT)
NCT01740479

Protocol serial number
15425

Study information

Scientific Title
A randomised, comparative effectiveness study of COMPLETE versus culprit-only revascularization strategies to treat multi-vessel disease after primary percutaneous coronary interventions (PCI) for ST-segment elevation myocardial infarction

Acronym
COMPLETE

Study objectives
The study is designed to determine whether, on a background of optimal medical therapy with low dose aspirin and ticagrelor, a strategy of multivessel revascularisation, involving staged PCI using drug eluting stents of all suitable non infarct related artery lesions, is superior to a strategy of culprit lesion only revascularisation in reducing the composite outcome of cardiovascular (CV) death or new Myocardial Infarction (MI) in patients with multivessel disease who have undergone successful culprit lesion primary PCI for STEMI.

Primary hypothesis: A strategy of complete revascularization will be superior to a strategy of culprit lesion only revascularization in reducing major clinical outcomes including the composite of CV death or new MI and the composite of death, new MI or ischemia-driven revascularization

Secondary hypothesis: A strategy of complete revascularization will lead to a better quality of life as measured by the EQ-5D and an improvement in angina control as measured by the Seattle Angina Questionnaire compared with a strategy of culprit lesion only revascularization.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee, 07/10/2013, 13/EM/0343

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

1. Complete Revascularisation: Staged PCI using second generation drug eluting stents of all suitable non-culprit lesions.
2. Culprit Only Revascularisation, Culprit Lesion-Only Revascularisation: no further revascularisation of non-culprit lesions.

This will be a randomised, comparative effectiveness study of complete versus culprit-only revascularisation strategies to treat multi-vessel disease after primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI).

Screening.
Patients, over the age of 18 years of age, who have undergone index PCI for STEMI and have at least one other non-culprit lesion in a vessel that is greater than or equal to 2.5 mm in diameter with at least 70% diameter stenosis (on visual estimation) or 50-69% stenosis with fractional flow reserve (FFR) less than or equal to 0.80, will be eligible to participate in the COMPLETE study. Index PCI for STEMI can be either primary PCI or rescue PCI for failed fibrinolysis or a pharmacoinvasive strategy where PCI is performed routinely 3-12 hours after initiation of fibrinolysis.

The direct clinical care team performing the primary PCI will be aware of the patient's suitability. The clinical care team, if the clinical situation allows, will ask the patient if they would be interested in helping with the study. The clinical care team will alert the research team, who will approach the patient and provide sufficient information for the patient to decide whether to participate in the study. If it is not appropriate, for clinical reasons, to discuss the study at the procedure, the interventionist or a member of the clinical care team may ask the patient following the procedure and when the patient is well enough. The research team can confirm the patient's suitability by accessing the database completed by the interventionist following the primary PCI. The study will be explained, in depth, to the patient by a research team member who will satisfactorily answer any questions that may arise and give the patient sufficient time to decide whether to participate in the study.

When written informed consent has been given by the patient, the research team will collect details of demographics, clinical assessment, medical history, concomitant medications, smoking status, blood pressure, lipid results including low-density lipoprotein (LDL) cholesterol, and glycaemic status (HbA1c). The research team will also assess Canadian Cardiovascular Society (CCS) classification, a measure of chest pain, and NYHA classification, a measure of heart failure severity, as well as ask the participant to complete a quality-of-life assessment.

Within 72 hours of the index PCI, the patient is randomised into one of the two study arms: complete revascularisation with background optimum medical therapy, or culprit-lesion-only revascularisation with background optimum medical therapy. Some of the assessments cited above are then repeated.

For those patients randomised to the complete revascularisation arm of the study, the staged PCI must be performed within 45 days. An electrocardiogram (ECG) is done within 12 hours prior to the procedure and 24 hours post procedure (or hospital discharge if earlier). At this time point, blood is drawn for cardiac markers and clinical outcomes and medical therapy is noted.

At hospital discharge, clinical outcomes, medical therapy, smoking status and CCS and NYHA classifications are documented. Six weeks into the study (plus or minus 14 days), the same information is collected again. This visit may be done either in a clinic or over the telephone.

At 6 months, a clinic visit (or optional telephone contact) is performed where the clinical outcomes, medical therapy, smoking status, serum LDL cholesterol, blood pressure, glycaemic status, quality of life assessments, and CCS and NYHA classifications are collected. Thereafter annual visits at 1,2,3 and 4 years are completed in the clinic or via telephone contact with documentation of clinical outcomes, medical therapy, smoking status, and CCS and NYHA classifications. The final visit/year 5 is a repeat of the month 6 visit, without the option of telephone contact.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Cardiovascular (CV) death or new MI; Timepoint(s): hospital discharge, 30 days, 6 months, 12 months and then annually for up to 5 years

Key secondary outcome(s))
1. To determine whether complete revascularisation reduces the composite of cardiovascular (CV) death, new Myocardial Infarction (MI) or ischaemia-driven revascularisation.
2. To determine whether the initial strategy of complete revascularisation improves angina control, as assessed by the Seattle Angina Questionnaire (SAQ) Frequency Scale, and health-related quality of life scale at 6 months and 5 years/final follow-up compared to baseline.

Other:
To determine whether an initial strategy of complete revascularisation is superior to an initial strategy of culprit lesion only revascularisation in reducing the composite of CV death, new MI, ischaemia-driven revascularisation or rehospitalisation for unstable angina or hospitalisation for heart failure and each component of the key secondary objectives taken separately as well as all-cause mortality, stroke, stent thrombosis, major bleeding, economic evaluation, including health resource utilization, costs and cost-effectiveness.

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Men and women within 72 hours after successful PCI (preferably using a drug-eluting stent) to the culprit lesion for STEMI. PCI for STEMI can be either primary PCI or rescue PCI for failed fibrinolysis or a pharmacoinvasive strategy where PCI is performed routinely 3-12 hours after initiation of fibrinolysis
2. Multi-vessel disease defined as at least 1 additional non-infarct related coronary artery lesion that is at least 2.5 mm in diameter that has not been stented as part of the primary PCI and that is amenable to successful treatment with PCI and has
2.1. at least 70% diameter stenosis (visual estimation) or

2.1. at least 50% diameter stenosis (visual estimation) with fractional flow reserve less than or equal to 0.80

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
4041

Key exclusion criteria
1. Planned revascularisation of non-culprit lesion(s)
2. Planned surgical revascularisation
3. Non-cardiovascular co-morbidity reducing life expectancy to less than 5 years
4. Any factor precluding 5 year follow up.
5. Prior coronary artery bypass graft (CABG) surgery.

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
United Kingdom

Australia

Brazil

Bulgaria

Canada

China

Czech Republic

Denmark

Finland

Germany

Greece

Hungary

Israel

Italy

Lithuania

Mexico

Netherlands

North Macedonia

Poland

Romania

Russian Federation

Serbia

Spain

Sweden

Ukraine

United States of America

Study participating centre
Population Health Research Institute, Canada
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Sponsor information

Organisation
Population Health Research Institute (Canada)

ROR

https://ror.org/03kwaeq96

Funder(s)

Funder type
Industry

Funder Name
Astra Zeneca (Canada)

Funder Name
Boston Scientific (USA)

Funder Name
Population Health Research Institute (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/10/2019	14/04/2021	Yes	No
HRA research summary			28/06/2023	No	No